



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,973	02/26/2002	James S. Norris	14017-004002 /PSU 96-1566	8113
26161 7590 01/11/2007 FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER EPPS FORD, JANET L	
			ART UNIT 1633	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/11/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/082,973		NORRIS ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Janet L. Epps-Ford		1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 October 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 39-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 39-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10-26-06 has been entered.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 39-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. (New Matter/Written description).

Applicants have amended the instant claims to recite, "wherein the sum of the number of nucleotides of said first and second arms is 25 nucleotides or more." The phrase "25 nucleotides or more" is an open-ended limitation, wherein there is no upper limit. The specification as filed, as referred to by Applicants in their support for the instant amendment provides only two examples, particularly Figure 3, wherein the 18:7

Art Unit: 1633

3' cis-acting ribozyme comprises a first and second arm totaling 25 nucleotides, and the 7:20 5' cis-acting ribozyme comprising arms totaling 27 nucleotides. However, other than these two examples, there is no support for ribozyme constructs of the present invention wherein there is no upper limit to the number of nucleotides comprised within the first and second arms of the claimed ribozyme constructs. Applicants amendment therefore is considered new matter since there is lack of sufficient antecedent basis for the newly added limitation of "wherein the sum of the number of nucleotides of said first and second arms is 25 nucleotides or more," recited in the instant claims. Applicants are requested to remove the new matter in response to this Action.

Additionally, instant claims 40-41 recite wherein said nucleotide sequence encodes a pChop cassette or a pSnip cassette. Other than the nucleotide sequences defined in the specification as filed, namely SEQ ID NO: 5, or as diagrammed in Figure 3, for the pCHOP cassette, or Figure 4 for the pSnip cassette it is unclear what other nucleotide structures define "*a pChop*" cassette or "*a pSnip*" cassette as defined by instant claims 40-41. Applicants have not provided any specific guidance as how to predict the structures of other nucleotide sequences (beyond the disclosure) that encode "*a pChop*" cassette or "*a pSnip*" cassette according to the present invention. See MPEP § 2163, which states, "[A] biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." In the instant case, Applicants have not disclosed any

Art Unit: 1633

particular correlation between the function of the "*pChop*" cassette or "*pSnip*" cassette according to the present invention and their corresponding structure, such that the skilled artisan would be able to immediately envision and predict the structures of other nucleic acid sequences encoding these constructs.

***Claim Rejections - 35 USC § 101***

4. 35 U.S.C. §101 states:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claim 53 is rejected under 35 USC §101 because the claimed invention is directed to non-statutory subject matter. The term "host cell" is defined by the specification in the following manner, see paragraph [0064]: "[I]n accordance with the invention, the host to which the multiple-ribozymes are delivered may be cells in culture, tissues in culture, plants, animal models, animals, mammals or humans." Therefore, the term "host cell" as defined by the specification is present or intended to be present in a human being, said cell becoming integrated into the human being and therefore being an inseparable part of the human itself. The scope of the claim, therefore, encompasses a human being, which is non-statutory subject matter. As such, the recitation of the limitation "non-human" would be remedial. See 1077 O.G. 24, April 21, 1987.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

7. Claims 39, and 43-48, 50-51, 53-55 are rejected under 35 U.S.C. 102(a) as being anticipated by Norris et al. (WO98/24,925).

Norris et al. teach nucleic acid molecules comprising tissue-specific and pathogen-specific promoters positioned upstream from a sequence from a sequence encoding ribozymes comprising a 5' autocatalytically cleaving ribozyme sequence, a catalytic ribozyme comprising a target RNA-specific binding site and a 3' autocatalytically cleaving ribozyme sequence. The Norris et al. reference further teaches wherein said catalytic ribozymes target rpoA, secA, ftsZ and dnaG RNA transcripts. This reference further teaches vectors comprising said nucleic acid molecules and those comprising multiple ribozyme structures, virions comprising said nucleic acid molecules, liposomes comprising said nucleic acid sequence, and methods for both treating and delivering said nucleic acid into cells. A specific example of a ribozyme construct disclosed by Applicants includes a construct against the secA gene inserted into the pClip vector (P. 44).

Additionally, Norris et al. teach lengthening the arms of the cis-acting ribozymes by 20 bases, this modification is disclosed as functioning to enhance the catalytic activity of the cis-acting elements (see page 21, last paragraph). See also Figures 5 and 6 wherein the arms of the cis-acting ribozymes are 25 nucleotides or more.


Art Unit: 1633

Norris et al. teach each and every aspect of the instant invention thereby anticipating applicant's claimed invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Janet L. Epps-Ford, Ph.D.  
Primary Examiner  
Art Unit 1633

JLE